UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MINNESOTA

In re: Levaquin Products Liability Litigation This document relates to: John Schedin v. Johnson & Johnson et al. Case No.: 0:08-cv-05743-JRT	Case No.: 0:08-md-01943-JRT **PLAINTIFF'S RESPONSE TO DEFENDANTS' FURTHER AUTHORITY IN SUPPORT OF MOTION *IN LIMINE* TO EXCLUDE PETITIONS TO FDA FROM PUBLIC CITIZEN AND THE ILLINOIS ATTORNEY GENERAL**

Plaintiff John Schedin, by and through his attorneys, respectfully submits this Response to Defendants' Further Authority in Support of Motion *in Limine* to Exclude Petitions to FDA from Public Citizen and the Illinois Attorney General ("Fur. Auth."). For the reasons stated herein and in Plaintiff's Consolidated Response to Defendants' Motions *in Limine* (Docket No. 97) ("Pltf. Res."), Defendants' motion should be denied.

ARGUMENT

Defendants offer little in the way of "further authority" in their brief, which consists largely of a rehash of their original arguments, and the addition of new arguments (as opposed to additional authority) they failed to raise previously. Their brief opens by mischaracterizing Plaintiff's response to their motion *in limine* with respect to the 2006 Public Citizen petition to the FDA. Defendants state that Plaintiff's response to their motion was to "substitute" the 2006 petition for Public Citizen's 1996

petition on Plaintiff's exhibits list. Fur. Auth. at [1].[1] In fact, the 2006 petition was always on Plaintiff's exhibits list;[2] it was Defendants who simply failed to object to it in their motion *in limine.* *See* Pltf. Res. at 6 & n.1.

Notice

Defendants next dispute the admissibility of the Citizen Petitions to demonstrate notice. Fur. Auth. at [1]-[2] Defendants offer no additional authority, but merely state that, since the Citizen Petitions post-date Plaintiff's use of Levaquin, they are not admissible to show notice to Defendants. They are, however, relevant to demonstrate notice to Defendants of the matters contained therein, which largely pre-date Plaintiff's use of Levaquin. "Notice" in this instance is not alleged on the basis that these matters were brought to Defendants' attention *by* the Citizen Petitions, but rather that the Citizen Petitions demonstrate that Defendants knew or should have known of the matters therein *prior* to Plaintiff using Levaquin.

Illinois Attorney General's Petition – Hearsay

To the extent that the Illinois Attorney General's petition were offered for a purpose to which a hearsay objection could be raised, Defendants contend that the petition would not be admissible as an investigative report based on factual findings under Fed. R. Evid. 803(8)(C) because it is not based on factual findings, was not prepared pursuant to legal authority, and is untrustworthy. Fur. Auth. at [2]-[4].

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[1] Page references to Defendants' brief appear in square brackets, since the pages of the brief are unnumbered.

[2] It was Exhibit 1268 on Plaintiff's original list. It is Exhibit 960 on Plaintiff's final numbered list.

Factual findings. The Illinois Attorney General petition states that, in response to complaints from Illinois citizens of "tendonopathies induced by their use of . . . Levaquin," it conducted an extensive review of medical literature and interviewed physicians on the staff of academic medical centers, which "led us to conclude that fluoroquinolone-induced tendonopathies are not a rare complication of fluoroquinolone use, and also to realize that this serious side-effect is not adequately appreciated by practicing physicians." Exh. B to Affidavit of Dana Lenahan (Docket No. 62) ("AG Pet.") at 3. In contrast to the DES task force report excluded in *Wetherill v. University of Chicago,* 518 F. Supp. 1387, 1390 (D. Ill. 1981) ("the task force never undertook or intended to undertake a factual investigation"), the Illinois Attorney General undertook to investigate the extent to which health care providers were aware of the risk of fluoroquinolone-induced tendinopathy, and concluded as a result of that investigation that enhanced warnings to physicians and patients were necessary. AG Pet. at 3-4. Defendants' characterization of the Attorney General petition as "an advocacy piece" notwithstanding, Fur. Auth. at [3], conclusions and opinions also are admissible under Rule 803(8)(C) if they are based on a factual investigation. *Beech Aircraft Corp. v. Rainey,* 488 U.S. 153, 170 (1988).

Authority granted by law. Defendants argument that the Illinois Attorney General lacked "authority granted by law" to prepare the petition is essentially that there is no case stating specifically that this particular action falls within the attorney general's common law authority. Fur. Auth. at [3]. Defendants, however, cite no case indicating a *limitation* on the attorney general's authority that would encompass this activity. They

suggest that all *Pioneer Processing, Inc. v. E.P.A.*, 464 N.E.2d 238 (Ill. 1984), establishes is that the attorney general "has standing to represent citizens in *legal actions*," Fur. Auth. at [3] (emphasis in original), and therefore that representing citizens in legal actions is the extent of the attorney general's authority. This is an absurdly narrow characterization of the powers of the Illinois attorney general.

The petition is signed by the Medical Directors of the Attorney General's Office and the office's Health Care Bureau. The bureau was opened in October 1998 to assist Illinois consumers with health care related problems. "Since then our staff has helped to clear up more than 8,000 complaints relating to health care issues." Illinois Attorney General – Health Care Assistance, http://www.illinoisattorneygeneral.gov/consumers/healthcare.html (last visited Nov. 7, 2010). Addressing health care related complaints from Illinois consumers is a regular activity of the Attorney General's office squarely within the scope of its legal authority.

Trustworthiness. Defendants previously contended that that the Illinois attorney general's petition was untrustworthy because the Attorney General's office was experienced in law, not medicine, Pltf. Mem. at 9, ignoring the existence of the office's Health Care Bureau. They now argue that the petition is untrustworthy because it relies on hearsay statements of third parties. Fur. Auth at [4].

An investigation of the awareness among doctors of the risks of fluoroquinolone-induced tendinopathy necessarily entails obtaining statements and information from third parties. Defendants, whose burden it is to "make an affirmative showing of untrustworthiness, beyond the obvious fact that the declarant is not in court to testify,"

Kehm v. Procter & Gamble Mfg. Co., 724 F.2d 613, 618 (8th Cir. 1983), have not suggested any reason why information obtained in the course of the investigation from physicians on the staff of academic medical centers should be considered untrustworthy. The investigation and petition were not untimely, they were not outside the expertise of the office's Health Care Bureau, nor is there any evidence of bias on the part of the attorney general's office, which are factors considered when evaluating the trustworthiness of an official report. *Beech Aircraft Corp. v. Rainey*, 488 U.S. at 167 n.11; *Complaint of Nautilus Motor Tanker Co.*, 862 F. Supp. 1251, 1255 (D.N.J. 1994) (absence of evidentiary hearing alone does not affect admissibility when other factors support trustworthiness). Moreover, the fact that the FDA ultimately took the course of action urged in the petition supports its trustworthiness. *See In re Ethylene Propylene Diene Monomer (EPDM) Antitrust Litig.*, 681 F. Supp. 2d 141, 155 (D. Conn. 2009).

2006 Public Citizen Petition - Hearsay

To the extent that the 2006 Public Citizen petition is offered for a purpose to which a hearsay objection could be raised, Defendants contend, without any citation to authority, additional or otherwise, that the petition would not be admissible under Fed. R. Evid. 803(6) as a business record, because it is based on adverse event reports ("AERs") and literature concerning which the authors do not have personal knowledge and which are untrustworthy, and because no one will testify as to whether documents like the 2006 petition are regularly prepared by Public Citizen. Fur. Auth. at [4]-[5].

The admissibility of both AERs and data and analysis derived from AERs are the subject of another defense motion *in limine* to which Plaintiff has responded. Pltf. Mem.

at 24-27. The petition itself, and Public Citizen's website, attest to the fact that Public Citizen regularly prepares submissions such as the 2006 petition (including its previous 1996 petition concerning fluoroquinolones). The 2006 petition submitted with Defendants' brief, which was downloaded from the Public Citizen website and introduced by Defendants as an exhibit in Dr. Blume's deposition, does not require someone from Public Citizen to testify to the fact that it is a document regularly prepared and kept by that organization.

Unfair Prejudice Substantially Outweighing Probative Value

Defendants contend that the Citizen Petitions "give the impression that they are based on an expert analysis," but that they "would not pass muster under *Daubert.*" Fur. Auth. at [5]. To the extent that any of Plaintiff's experts may rely on either of the Citizen Petitions or the information contained therein, Defendants have had the opportunity to file *Daubert* motions challenging the admissibility of such testimony. If they wished to file motions to exclude the Citizen Petitions themselves under *Daubert*, they should have done so when such motions were due.

Defendants argue that the petitions contain language "suggesting misconduct . . . where no such evidence exists to support such a contention." Fur. Auth. at [5]-[6]. Plaintiff, of course, contends otherwise, and will offer substantial evidence of misconduct by Defendants. In any case, Defendants' cursory speculation regarding potential juror confusion hardly satisfies their burden of demonstrating *unfair* prejudice that would *substantially* outweigh the probative value of this evidence. *See, e.g., Gross v. Black & Decker (U.S.), Inc.*, 695 F.2d 858, 863 (5th Cir. 1983).

CONCLUSION

For the reasons stated herein, Plaintiff respectfully submits that Defendants' motion *in limine* to exclude the Illinois Attorney General and Public Citizen petitions to the FDA should be denied.

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Respectfully submitted,

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